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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/648,816	08/25/2000	Michael R. Yeaman	660081.415C1	6324

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/648,816

Applicant(s)

YEAMAN ET AL.

Examiner

Chih-Min Kam

Art Unit

1653

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19 April 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 67-69 and 75.

Claim(s) withdrawn from consideration: 70-74 and 76-79.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Continuation of 2. NOTE: In the amendment of April 19, 2004, claim 67 has been amended to cite the term "synthetic peptide mimetics thereof" to clarify that naturally occurring amino acids are not encompassed as mimetics of the invention. Applicants' response has been fully considered, however, claims 67-69 and 75 are rejected under 35 U.S.C. 112, second paragraph, and under 35 U.S.C. 102 (b).

If applicants' amendment to claim 67 were entered, it would have the following response:

1. Claims 67-69 and 75 are rejected under 35 USC 112, second paragraph as being indefinite because of the use of the term "synthetic peptide mimetics thereof". The term "synthetic peptide mimetics thereof" renders the claim indefinite, it is unclear what structures the peptide mimetics have, and how different the peptide mimetic is from the parent peptide. Claims 68, 69 and 75 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend. In response, applicants indicate the term "mimetics thereof" is definite in view of the teachings in the specification and what was known in the art, the skilled person would have understood the term "mimetics thereof" by teaching, e.g., the invention peptide can be conformationally stabilized by replacing selected amino acid in the original peptide chain with amino acids that restrict the motion of the peptide chain, e.g., beta-branched, N-methyl, alpha, beta-dehydro, alpha, alpha-dialkyl and D- amino acids, and the substitutions with D- and other unusual amino acids into peptide templates can extend the half-life of the invention peptide. The skilled person would have understood with clarity that mimetics include peptidomimetics, peptoids or other peptide-like polymers or other non-polymeric compounds having functional groups that mimic a peptide as positioned. With regard to the art-knowledge, the manufacture of "peptidomimetics" and the scope of the term itself were well known in the art as evidenced by the exhibits previously submitted by the applicant. Applicants also replace the term "mimetics" with "synthetic peptide mimetics" to clarify that naturally occurring amino acids are not encompassed as mimetics of the invention (pages 4-6 of the response). The response has been considered, but the argument is not found persuasive because the specification at page 42, lines 12-21 describes "synthetic analogs" of selected peptides having antimicrobial activities (see page 42, line 9-12), not "mimetics" of the antimicrobial peptides, and the two references previously provided by the applicants also describe "peptidomimetics", which is a subgroup of mimetics, the "mimetics" may include peptidomimetics, peptoids, other peptide-like polymers or other non-polymeric compounds having functional groups that mimic a peptide as positioned. Since neither the claim nor specification specifically define the term "mimetics thereof", thus it is not clear what structures or sequences the mimetics would have. The term "synthetic peptide mimetics thereof" only indicates the peptide mimetic is synthetic, it does not necessarily mean each monomer of peptide is synthetic, not naturally occurring.

2. Claims 67-69 and 75 are rejected under 35 U.S.C. 102(b) as anticipated by Darveau et al. (U. S. Patent 5,409,898).

Darveau et al. disclose a synthetic cationic oligopeptide such as Ala-Leu-Tyr-Lys-Lys-Leu-Leu-Lys-Lys-Leu-Leu-Lys-Ser-Ala-Lys-Lys-Leu-Gly which has a helical amphiphilic antibacterial activity (column 12, lines 31-32 and 49-54), this peptide is the mimetic of SEQ ID NO:3 (Ala-Leu-Tyr-Lys-Lys-Phe-Lys-Lys-Lys-Leu-Leu-Lys-Ser-Leu-Lys-Arg-Leu-Gly; claims 67-69) or SEQ ID NO:9 (Ala-Leu-Tyr-Lys-Lys-Trp-Lys-Asn-Lys-Leu-Leu-Lys-Ser; claim 75) that retains antimicrobial activity. Since neither the claim nor the specification clearly defines the term "mimetics thereof", any substituted peptide which retains antimicrobial activity would meet the criteria of the claim. In response, applicants indicate the peptides in '898 patent differ from the claimed antimicrobial peptides by having non-identical natural amino acid residues at several positions, while mimetics are "chemical structures derived from bioactive peptides which imitate natural molecules" as indicated in Goodman and Ro; and applicants also replace the term "mimetics" with "synthetic peptide mimetics" to clarify that naturally occurring amino acids are not encompassed as mimetics of the invention (page 7 of the response). The response has been considered, however the argument is not found persuasive because Goodman and Ro defines "peptidomimetics" are "chemical structures derived from bioactive peptides which imitate natural molecules" (at paragraph bridging pages 804 and 805), as indicated in applicant's response, the mimetics include not only peptidomimetics but also other peptide-like structures, and the term has not been clearly defined in the specification. Furthermore, the term "synthetic peptide mimetics thereof" only indicates the peptide mimetic is synthetic, it does not necessarily mean each monomer of peptide is synthetic, not naturally occurring.

Continuation of 3. Applicant's reply has overcome the following rejection(s): If entered, the rejection of claims 67 and 68 under USC 102 (b) as anticipated by Kupsch et al. (The EMBO J. 12, 641-650 (1993)).

Continuation of 5. does NOT place the application in condition for allowance because: claims 67-69 and 75 are rejected under 35 U.S.C. 112, second paragraph, and 35 U.S.C. 102 (b).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D.
Patent Examiner

CMK

April 30, 2004


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